

## § 73.2500

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification pursuant to section 721(c) of the act.

[42 FR 38561, July 29, 1977]

## § 73.2500 Silver.

(a) *Identity.* (1) The color additive, silver, is a crystalline powder of high purity silver prepared by the reaction of silver nitrate with ferrous sulfate in the presence of nitric, phosphoric and sulfuric acids. Polyvinyl alcohol is used to prevent the agglomeration of crystals and the formation of amorphous silver.

(2) Color additive mixtures of silver may contain only those diluents listed in § 73.1001(b) and, in addition, nitrocellulose.

(b) *Specifications.* Silver shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 5 parts per million.

Mercury (as Hg), not more than 1 part per million.

Silver (as Ag), not less than 99.9 percent.

(c) *Uses and restrictions.* The color additive silver may be safely used for coloring fingernail polish at a level not to exceed 1 percent of the final product.

(d) *Labeling.* The color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any other information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[44 FR 65974, Nov. 16, 1979]

## § 73.2575 Titanium dioxide.

(a) *Identity and specifications.* The color additive titanium dioxide shall conform in identity and specifications

## 21 CFR Ch. I (4–1–10 Edition)

to the requirements on § 73.575 (a)(1) and (b).

(b) *Uses and restrictions.* The color additive titanium dioxide may be safely used in cosmetics, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any other information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 721(c) of the act.

## § 73.2645 Aluminum powder.

(a) *Identity and specifications.* The color additive aluminum powder shall conform in identity and specifications to the requirements of § 73.1645 (a)(1) and (b).

(b) *Uses and restrictions.* Aluminum powder may be safely used in coloring externally applied cosmetics, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification pursuant to section 721(c) of the act.

[42 FR 38563, July 29, 1977]

## § 73.2646 Bronze powder.

(a) *Identity and specifications.* The color additive bronze powder shall conform in identity and specifications to the requirements of § 73.1646 (a)(1) and (b).

(b) *Uses and restrictions.* Bronze powder may be safely used in coloring cosmetics generally, including cosmetics intended for use in the area of the eye,

in amounts consistent with good manufacturing practice.

(c) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of the color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 33724, July 1, 1977]

#### § 73.2647 Copper powder.

(a) *Identity and specifications.* The color additive copper powder shall conform in identity and specifications to the requirements of § 73.1647 (a)(1) and (b).

(b) *Uses and restrictions.* Copper powder may be safely used in coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of the color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 33724, July 1, 1977]

#### § 73.2725 Ultramarines.

(a) *Identity.* The color additives, ultramarines (blue, green, pink, red, and violet) are pigments obtained by calcining at temperatures above 700 °C. a mixture of kaolin, sulfur, sodium carbonate, silicious matter, sodium sulfate, and carbonaceous matter, but not necessarily all these substances, to produce a single color. The ultramarines are complex sodium aluminum sulfosilicates having a typical formula  $\text{Na}(\text{AlSiO})\text{S}$  with proportions of each element varying with each color.

(b) *Specifications.* The ultramarines shall conform to the following specifications and shall be free from impuri-

ties other than those named, to the extent that such other impurities may be avoided by good manufacturing practice.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* The ultramarine pigments may be safely used for coloring externally applied cosmetics, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling requirements.* The color additives and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any other information required by law, labeling in accordance with § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 721(c) of the act.

#### § 73.2775 Manganese violet.

(a) *Identity.* The color additive manganese violet is a violet pigment obtained by reacting phosphoric acid, ammonium dihydrogen orthophosphate, and manganese dioxide at temperatures above 450 °F. The pigment is a manganese ammonium pyrophosphate complex having the approximate formula:  $\text{Mn(III)NH}_4\text{P}_2\text{O}_7$ .

(b) *Specifications.* Manganese violet shall conform to the following specifications and shall be free from impurities other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Ash (at 600 °C), not less than 81 percent.

Volatile matter at 135 °C for 3 hours, not more than 1 percent.

Water soluble substances, not more than 6 percent.

pH of filtrate of 10 grams color additive (shaken occasionally for 2 hours with 100 milliliters of freshly boiled distilled water), not more than 4.7 and not less than 2.5.

Lead (as Pb), not more than 20 parts per million.